

REMARKS

This Amendment is filed in response to the Final Office Action mailed August 14, 2007. In this Amendment, claims 79, 118, 124 and 126 are amended and claims 80-106, 111-117, 119-123, 125 and 127-128 are unchanged. Following entry of this amendment, claims 79-106 and 111-128 shall be pending.

In the Office Action, claim 126 is rejected because of indefiniteness, and claims 79-106 and 111-128 have been rejected based on prior art grounds. For the reasons set forth below, these rejections are hereby traversed.

I. REJECTIONS UNDER 35 U.S.C. SECTION 112

The Examiner rejected claim 126 under 35 U.S.C. 112, second paragraph, as being indefinite because “the perigraft space” lacks antecedent basis. In an effort solely to expedite prosecution of this application, claim 126 has been amended to recite “the aneurysm”. It is believed that the basis for the Section 112 rejection is no longer present and therefore it is requested that this rejection be withdrawn.

II. REJECTIONS UNDER 35 U.S.C. SECTION 102

Claims 124, 125 and 127 are rejected under 35 U.S.C. Section 102(e) as being anticipated by U.S. Patent No. 6,730,119 to Smalling (*The Smalling Patent*). For at least the reasons set forth below, it is submitted that these prior art rejections should be withdrawn and the pending claims allowed.

Turning first to claim 124, this claim as now amended is directed to a method of treating an aneurysm of a vessel comprising advancing a distal end of a cannula to an aneurysm; positioning an endovascular graft near said aneurysm; anchoring said endovascular graft to a wall of the vessel over said aneurysm; capturing said cannula between an outside surface of said graft and an inside surface of said vessel wall; delivering an expansile material into said aneurysm through said cannula.

The Smalling Patent cannot be properly relied upon as rendering obvious the invention as recited in claim 124. For example, *The Smalling Patent* fails to teach capturing said cannula between an outside surface of said graft and an inside surface of said vessel wall. As best understood, *The Smalling Patent* discloses delivering a stent over an aneurysm, then penetrating the stent with a delivery device to deliver embolization material. Thus, the *Smalling* technique requires positioning and manipulation of the distal end of the delivery device that is altogether different from what is contemplated by the present invention.

The Examiner argues that *The Smalling Patent* discloses “capturing” with “a cell in the wall of the graft and with the graft outer covering”. However, the Examiner’s characterization of *Smalling* emphasizes that only the graft captures the cannula. Claim 124 previously recited that the cannula was captured between the graft and the vessel, not by the graft alone.

Nonetheless, in an effort to add clarity, this claim has been amended to recite capturing said cannula between an outside surface of said graft and an inside surface of said vessel wall. In contrast, *The Smalling Patent* only shows piercing the stent with a delivery device and in no way discloses capturing the cannula as now recited in claim 124. Thus, for at least this reason, *The Smalling Patent* fails to anticipate claim 124. It is also submitted that *The Smalling Patent* fails to render the invention obvious.

Turning to claims 125-128, these claims depend from claim 124 and thus for at least the above reasons are also novel and unobvious over the cited prior art. However, these claims further limit the claimed invention and thus are separately patentable over the cited prior art.

III. REJECTIONS UNDER 35 U.S.C. SECTION 103

Claims 79-95, 100-106, 112, 114-116, 118-120, 122-124, 126 and 128 are rejected under 35 U.S.C. Section 103(a) as being anticipated by U.S. Publication No. 2002/0169497 to Wholey et al. (*The Wholey et al. Publication*) in view of U.S. Patent

No. 6,238,403 to Greene, Jr. et al. (*The Greene, Jr. et al Patent*). For at least the reasons set forth below, it is submitted that these prior art rejections should be withdrawn and the pending claims allowed.

Claim 79 is directed to a method for preventing leakage into a perigraft space between an endovascular graft that has been implanted in the lumen of a blood vessel of a human or veterinary patient and an adjacent portion of the blood vessel wall, said method comprising the steps of: (A) providing a device comprising a solid member having expansile polymeric material disposed thereon, said expansile polymeric material being i) initially in a non-expanded state wherein a quantity of the polymeric material occupies a first volume and b) subsequently expandable to an expanded state wherein said quantity of the polymeric material occupies a second volume larger than the first volume and absorbs blood; (B) inserting a cannula into said lumen of the blood vessel; (C) disposing said endovascular graft over a distal end of said cannula and over said adjacent portion of said blood vessel wall such that said distal end of said cannula is captured between an external surface of said endovascular graft and a wall of said blood vessel that mates with said external surface of said endovascular graft; (D) introducing said device through said cannula and into a perigraft space between said endovascular graft and said blood vessel wall while said expansile polymeric material is substantially in its non-expanded state; (E) allowing said polymeric material to expand to its expanded state within said perigraft space such that said device substantially fills said perigraft space.

The Wholey et al. Publication cannot be properly relied upon in this obviousness rejection of claim 79. For example, *The Wholey et al. Publication* does not teach disposing said endovascular graft over a distal end of said cannula and over said adjacent portion of said blood vessel wall such that said distal end of said cannula is captured between an external surface of said endovascular graft and a wall of said blood vessel that mates with said external surface of said endovascular graft as claimed. *The Wholey et al. Publication* discloses delivering a graft over an aneurysm, then penetrating the graft at a small port with a delivery device. Thus, the *Wholey*

technique requires positioning and manipulation of the distal end of the delivery device that is altogether distinct from the present invention.

The Examiner argues that *The Wholey et al. Publication* teaches that a disposed graft can be said to be 'over' the cannula because "when the distal end of the cannula has reached the vicinity of the perigraft space or aneurysm, the lumen of the graft surrounds the distal end and is 'over' the cannula like a sleeve." While the undersigned disagrees with the Examiners interpretation of *The Wholey et al. Publication*, claim 79 has been amended to clarify the invention and further distant the claimed invention from *The Wholey et al. Publication*. In particular, claim 79 now includes the act of disposing said endovascular graft over a distal end of said cannula and over said adjacent portion of said blood vessel wall such that said distal end of said cannula is captured between an external surface of said endovascular graft and a wall of said blood vessel that mates with said external surface of said endovascular graft as recited. The undersigned finds no such disclosure in *The Wholey et al. Publication*.

The Greene, Jr. et al. Patent does not make up for this deficiency of *The Wholey et al. Publication*. *The Greene, Jr. et al. Patent* may teach a microcoil with expandable pellets, however the undersigned is unable to find any disclosure of disposing said endovascular graft over a distal end of said cannula and over said adjacent portion of said blood vessel wall such that said distal end of said cannula is captured between an external surface of said endovascular graft and a wall of said blood vessel that mates with said external surface of said endovascular graft as recited in claim 79.

Hence, it is clear that *The Wholey et al. Publication* cannot be properly relied upon to reject claim 79. Nor does *The Greene, Jr. et al. Patent* make up for the deficiencies of *The Wholey et al. Publication*. Accordingly, it is submitted that the rejection of claim 79 based on *The Wholey et al. Publication* and *The Greene, Jr. et al. Patent* should be withdrawn.

Claim 79 was also rejected based on *The Smalling Patent* in view of *The Greene, Jr. et al. Patent*. *The Smalling Patent* cannot be properly relied upon as rendering

obvious the invention as recited in claim 79. For example, *The Smalling Patent* does not teach disposing said endovascular graft over a distal end of said cannula and over said adjacent portion of said blood vessel wall such that said distal end of said cannula is captured between an external surface of said endovascular graft and a wall of said blood vessel that mates with said external surface of said endovascular graft as claimed. As best understood, *The Smalling Patent* discloses delivering a stent over an aneurysm, then penetrating the stent with a delivery device to deliver embolization material. Thus, the *Smalling* technique requires positioning and manipulation of the distal end of the delivery device that is altogether distinct from the present invention.

The Examiner argues that *The Smalling Patent* teaches that a disposed graft can be said to be 'over' the cannula because "when the distal end of the cannula has reached the vicinity of the perigraft space or aneurysm, the lumen of the graft surrounds the distal end and is 'over' the cannula like a sleeve. While the undersigned disagrees with the Examiners interpretation of *The Smalling Patent*, claim 79 has been amended to clarify the invention. In this respect, claim 79 now recites disposing said endovascular graft over a distal end of said cannula and over said adjacent portion of said blood vessel wall such that said distal end of said cannula is captured between an external surface of said endovascular graft and a wall of said blood vessel that mates with said external surface of said endovascular graft as recited. The undersigned finds no such disclosure in *The Smalling Patent*.

As previously discussed with regard to *The Wholey et al. Publication*, *The Greene, Jr. et al. Patent* does not make up for this deficiency of *The Smalling Patent*. *The Greene, Jr. et al. Patent* may teach a microcoil with expandable pellets, however the undersigned is unable to find any disclosure of disposing said endovascular graft over a distal end of said cannula and over said adjacent portion of said blood vessel wall such that said distal end of said cannula is captured between an external surface of said endovascular graft and a wall of said blood vessel that mates with said external surface of said endovascular graft as recited in claim 79.

Turning to claims 80-106 and 111-117, these claims depend from claim 79 and thus for at least the above reasons are also novel and unobvious over the cited prior art. However, these claims further limit the claimed invention and thus are separately patentable over the cited prior art.

Claim 118 is directed to a method of treating a vessel within a body comprising: positioning a distal end of a delivery device in proximity of a target location within said vessel; expanding a graft at said target location within said vessel such that a perigraft space is formed, said graft expanding over said distal end of said delivery device and thereby holding said distal end of said delivery device by pressing said distal end between an external surface of said graft and an internal surface of said vessel; and introducing an expansile material into said perigraft space through said delivery device; expanding said expansile material within said perigraft space.

The Wholey et al. Publication cannot be properly relied upon as rendering obvious the invention as recited in claim 118. For example, *The Wholey et al. Publication* does not teach expanding a graft at said target location within said vessel such that a perigraft space is formed, said graft expanding over said distal end of said delivery device and thereby holding said distal end of said delivery device by pressing said distal end between an external surface of said graft and an internal surface of said vessel as claimed. *The Wholey et al. Publication* discloses delivering a graft over an aneurysm, then penetrating the graft at a small port with a delivery device. Thus, the *Wholey* technique requires positioning and manipulation of the distal end of the delivery device that is altogether distinct from the present invention.

The Examiner argues that *The Wholey et al. Publication* teaches that a disposed graft can be said to be over the cannula because "when the distal end of the cannula has reached the vicinity of the perigraft space or aneurysm, the lumen of the graft surrounds the distal end and is 'over' the cannula like a sleeve". While the undersigned disagrees with the Examiners interpretation of *The Wholey et al. Publication*, claim 118 has been amended to clarify the invention. Claim 118 now recites expanding a graft at

said target location within said vessel such that a perigraft space is formed, said graft expanding over said distal end of said delivery device and thereby holding said distal end of said delivery device by pressing said distal end between an external surface of said graft and an internal surface of said vessel as recited. The undersigned finds no such disclosure in *The Wholey et al. Publication*.

The Greene, Jr. et al. Patent does not make up for this deficiency of *The Wholey et al. Publication*. *The Greene, Jr. et al. Patent* may teach a microcoil with expandable pellets, however the undersigned is unable to find any disclosure of expanding a graft at said target location within said vessel such that a perigraft space is formed, said graft expanding over said distal end of said delivery device and thereby holding said distal end of said delivery device by pressing said distal end between an external surface of said graft and an internal surface of said vessel as recited in claim 118.

Hence, it is clear that *The Wholey et al. Publication* cannot be properly relied upon to reject claim 118. Nor does *The Greene, Jr. et al. Patent* make up for the deficiencies of *The Wholey et al. Publication*. Accordingly, it is submitted that the rejection of claim 118 based on *The Wholey et al. Publication* and *The Greene, Jr. et al. Patent* should be withdrawn.

Claim 118 was also rejected based on *The Smalling Patent* in view of *The Greene, Jr. et al. Patent*. *The Smalling Patent* cannot be properly relied upon as rendering obvious the invention as recited in claim 118. For example, *The Smalling Patent* does not teach expanding a graft at said target location within said vessel such that a perigraft space is formed, said graft expanding over said distal end of said delivery device and thereby holding said distal end of said delivery device by pressing said distal end between an external surface of said graft and an internal surface of said vessel as claimed. As best understood, *The Smalling Patent* discloses delivering a stent over an aneurysm, then penetrating the stent with a delivery device to deliver embolization material. Thus, the *Smalling* technique requires positioning and

manipulation of the distal end of the delivery device that is altogether distinct from the present invention.

The Examiner argues that *The Smalling Patent* teaches that a disposed graft can be said to be 'over' the cannula because "when the distal end of the cannula has reached the vicinity of the perigraft space or aneurysm, the lumen of the graft surrounds the distal end and is 'over' the cannula like a sleeve". While the undersigned disagrees with the Examiners interpretation of *The Smalling Patent*, claim 118 has been amended to clarify the invention. Claim 118 has been amended to recite expanding a graft at said target location within said vessel such that a perigraft space is formed, said graft expanding over said distal end of said delivery device and thereby holding said distal end of said delivery device by pressing said distal end between an external surface of said graft and an internal surface of said vessel as recited. The undersigned finds no such disclosure in *The Smalling Patent*.

As previously discussed with regard to *The Wholey et al. Publication*, *The Greene, Jr. et al. Patent* does not make up for this deficiency of *The Smalling Patent*. *The Greene, Jr. et al. Patent* may teach a microcoil with expandable pellets, however the undersigned is unable to find any disclosure of expanding a graft at said target location within said vessel such that a perigraft space is formed, said graft expanding over said distal end of said delivery device and thereby holding said distal end of said delivery device by pressing said distal end between an external surface of said graft and an internal surface of said vessel as recited in claim 118.

Turning to claims 119-123, these claims depend from claim 118 and thus for at least the above reasons are also novel and unobvious over the cited prior art. However, these claims further limit the claimed invention and thus are separately patentable over the cited prior art.

Claim 124 is directed to a method of treating an aneurysm of a vessel comprising advancing a distal end of a cannula to an aneurysm; positioning an endovascular graft near said aneurysm; anchoring said endovascular graft to a wall of the vessel over said

aneurysm; capturing said cannula between an outside surface of said graft and an inside surface of said vessel wall; delivering an expansile material into said aneurysm through said cannula.

The Wholey et al. Publication cannot be properly relied upon as rendering obvious the invention as recited in claim 124. For example, *The Wholey et al. Publication* does not teach capturing said cannula between an outside surface of said graft and an inside surface of said vessel wall as claimed. *The Wholey et al. Publication* discloses delivering a graft over an aneurysm, then penetrating the graft at a small port with a delivery device. Thus, the *Wholey* technique requires positioning and manipulation of the distal end of the delivery device that is altogether distinct from the present invention.

The Examiner argues that *The Wholey et al. Publication* teaches that a disposed graft can be said to be over the cannula because “when the distal end of the cannula has reached the vicinity of the perigraft space or aneurysm, the lumen of the graft surrounds the distal end and is ‘over’ the cannula like a sleeve. While the undersigned disagrees with the Examiners interpretation of *The Wholey et al. Publication*, claim 124 has been amended to clarify the invention. Claim 124 now recites capturing said cannula between an outside surface of said graft and an inside surface of said vessel wall as recited. The undersigned finds no such disclosure in *The Wholey et al. Publication*.

The Greene, Jr. et al. Patent does not make up for this deficiency of *The Wholey et al. Publication*. *The Greene, Jr. et al. Patent* may teach a microcoil with expandable pellets; however, the undersigned is unable to find any disclosure of capturing said cannula between an outside surface of said graft and an inside surface of said vessel wall as recited in claim 124.

Hence, it is clear that *The Wholey et al. Publication* cannot be properly relied upon to reject claim 124. Nor does *The Greene, Jr. et al. Patent* make up for the deficiencies of *The Wholey et al. Publication*. Accordingly, it is submitted that the

rejection of claim 124 based on *The Wholey et al. Publication* and *The Greene, Jr. et al. Patent* should be withdrawn.

Claim 124 was also rejected based on *The Smalling Patent* in view of *The Greene, Jr. et al. Patent*. *The Smalling Patent* cannot be properly relied upon as rendering obvious the invention as recited in claim 124. For example, *The Smalling Patent* does not teach capturing said cannula between an outside surface of said graft and an inside surface of said vessel wall as claimed. As best understood, *The Smalling Patent* discloses delivering a stent over an aneurysm, then penetrating the stent with a delivery device to deliver embolization material. Thus, the *Smalling* technique requires difficult positioning and manipulation of the distal end of the delivery device.

The Examiner argues that *The Smalling Patent* teaches that a disposed graft can be said to be 'over' the cannula because "when the distal end of the cannula has reached the vicinity of the perigraft space or aneurysm, the lumen of the graft surrounds the distal end and is 'over' the cannula like a sleeve". While the undersigned disagrees with the Examiners interpretation of *The Smalling Patent*, claim 124 has been amended to clarify the invention. Claim 124 now recites capturing said cannula between an outside surface of said graft and an inside surface of said vessel wall as recited. The undersigned finds no such disclosure in *The Smalling Patent*.

As previously discussed with regard to *The Wholey et al. Publication*, *The Greene, Jr. et al. Patent* does not make up for this deficiency of *The Smalling Patent*. *The Greene, Jr. et al. Patent* may teach a microcoil with expandable pellets; however, the undersigned is unable to find any disclosure of capturing said cannula between an outside surface of said graft and an inside surface of said vessel wall as recited in claim 124.

Turning to claims 125-128, these claims depend from claim 124 and thus for at least the above reasons are also novel and unobvious over the cited prior art. However, these claims further limit the claimed invention and thus are separately patentable over the cited prior art.

CONCLUSION

In view of the foregoing, it is submitted that pending claims 79-106 and 111-128 are now in condition for allowance. Hence an indication of allowability is hereby requested.

If for any reason direct communication with Applicants' attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-2809.

Respectfully submitted,

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